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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,783	09/23/2003	Miroslav Smriga	241244USOCONT	9560
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
05/15/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/667,783

Applicant(s)

SMRIGA ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 24-26, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 27 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed February 21, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejections)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The claims recite the terms "irritable colon syndrome" and "irritable bowel syndrome". These two conditions appear to mean the same thing.

2) Claim 13 recites the limitation "stress loading". The term "stress loading" is confusing and it cannot be determined what the term encompasses. Also, the term "stress loading" in claim 3 is a relative term which renders the claim indefinite. The term "stress loading" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

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not be reasonably apprised of the scope of the invention. The term implies some extreme amount of stress and it cannot be determined how much stress the term encompasses.

3) Claim 13 recites "entails providing". The addition of "entails" makes the term "providing" indefinite, because it is appended to a term that is otherwise definite, therefore modifying its function is unclear. It is suggested that Applicant delete the term "entails".

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

1) Claims 1-11, 13, 15-20, 22-23, 27, 30-43, 45, 47-52 and 54-56 were rejected under 35 U.S.C. 102(b) as being anticipated by Schaefer et al. (US 5,505,968). The rejection is maintained in regards to claims 1-11, 13, 15-20, 22, 23, 27, and 30-32.

Applicant's Arguments

Applicant argues that panic disorders and general anxiety disorder are art recognized terms and that the recognized definition for these terms would exclude "antemortem stress". Applicant has submitted evidence to support this position. The essential characteristics of general anxiety disorder are sustained and excessive anxiety and worry accompanied by a number of physiological symptoms. According to ICD-10, there must have been a period of at least 6 months with prominent tension, worry, and feeling of apprehension about every day events and problems. In the case of panic disorder of ICD-10, the panic attacks are not associated with marked exertion or

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with exposure to dangerous of life threatening situations. This argument is not persuasive.

Examiner's Response

The evidence Applicant has submitted is in reference to a human subject and not an animal subject such as cattle, fish, pigs and chickens. Nowhere does Applicant provide evidence of how these disorders affect animals or how to identify the symptoms when manifested in an animal other than human. Applicant has acknowledged that Schaefer et al.'s definition for antemortem stress includes "stresses imparted during other animal marketing practices, such as transporting animals for other than slaughter purposes". These would include everyday events such as herding cattle, which would fall under Applicant's characterization of generalized anxiety disorder wherein the cattle have prominent tensions, worry and feelings of apprehension about everyday events and problems such as transportation.

Claim Rejections - 35 USC § 102 - Anticipation (New Rejection)

1) Claims 1-3, 13, 15, 20, 21, 23 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Niebes et al. (US 4,507,314).

Niebes et al. disclose a composition for treating stress induced ulcers comprising L-lysine. The ulcers include gastric ulcers. The compositions may also include L-arginine and L-ornithine. Although the lysine is used mainly as a reaction product with catechin, it is also added alone in injectable compositions (see col. 6, lines 15-20). The

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reference anticipates the instant claims insofar as it discloses a method of treating gastric ulcers with lysine.

2) Claims 1, 2, 4, 5, 13, 15-23 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Krnjec (US 4,405,610).

Krnjec disclose compositions for treating conditions such as gastric ulcers with compositions comprising lysine orotate (col. 1, lines 19-26). The drug was given to patients in a dose of 25 mg a day and was usually administered in tea or undiluted milk. When in liquid form, 1.5 ml of composition with a concentration of 3 mg/ml (0.3%) is administered per 0.25 kg of body weight (18 mg per kg per body) (see claim 1). The reference anticipates the instant claims insofar as it discloses a method of treating gastric ulcers with lysine.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 12 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. (US 5,505,968). The rejection is maintained in regards to claim 12. Claim 44 has been cancelled.

See Applicant's arguments and Examiner's response supra.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-17, 20-23, 27, 30-47 and 52-56 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,525,102) in view of Pitman (US 2004/0005311). The rejection is maintained in regards to claims 1-17, 20-23, 27 and 30-32. Claims 33-47 and 52-56 are cancelled.

Applicant's Arguments

Applicant argues the anxiety in Pitman does not qualify in the clinically recognized classes of individuals referred to by the term "anxiety disorders" in the present application. Chen does not specifically disclose or suggest administering a composition containing lysine to treat anxiety disorders. There is no motivation to administer lysine together with B-interferon, much less for the treatment of anxiety disorders. The combined disclosures do not render the invention of the instant claims obvious. Furthermore the amino acids are used in the compositions for a different function than that recited by the instant claims. In addition memory loss and anxiety disclosed by Pitman is dementia related symptoms and further points out anxiety is not included in the diagnostic standard of Dementia. The anxiety of the recited disorders is a "feeling of dread" which is different from fear. Thus memory loss and anxiety is quite different from anxiety disorder. This argument is not persuasive.

Examiner's Response

Pitman has disclosed lysine reduces anxiety and Applicant has provided no evidence to show that treatment of anxiety is dependent on the condition. It would have been obvious to incorporate a preferred ingredient into a composition that has been

disclosed to use that ingredient when treating one of the conditions the compositions is disclosed to be used for, in the case of Chen anxiety disorders, because the preferred compound has been disclosed in the art to treat a major symptom of the disorder, anxiety. The motivation to combine B-interferon with lysine is the disclosure by Chen that lysine is a preferred component of the compositions. Although lysine is used for a different purpose in Chen, it will inherently have the function of treating anxiety especially when the compositions of Chen are used to treat anxiety disorders. Anxiety is a symptom of many disorders such as dementia as well as those disorders recited by the instant claims and is induced by stress. Anxiety is defined as "a state of uneasiness and apprehension, as about future uncertainties; in psychiatry: a state of apprehension, uncertainty, and fear resulting from the anticipation of a realistic or fantasized threatening event or situation, often impairing physical and psychological functioning; or eager, often agitated desire: *my anxiety to make a good impression.*"¹ There appears to be no indication that treating anxiety with a compound due to one condition cannot be used to treat anxiety due to another and Applicant has asserted that anxiety is not included in diagnostic standard of Dementia. It may be concluded that treating anxiety generally will treat the condition no matter of its related cause or condition such as general anxiety disorder or dementia.

¹ "anxiety." The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. *Answers.com* 07 May. 2008. <http://www.answers.com/topic/anxiety>

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Claims 1-23, 27, and 30-32 are rejected.

Claims 24-26, 28-29 and 57-58 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612